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SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.
P.O. BOX 2938
MINNEAPOLIS, MN 55402

EXAMINER	
REIDEL, JESSICA L	

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/670,985
Filing Date: September 25, 2003
Appellant(s): RUGNETTA ET AL.

Nicole R. Kramer
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 1/15/2007 appealing from the Office action mailed 6/13/2006.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

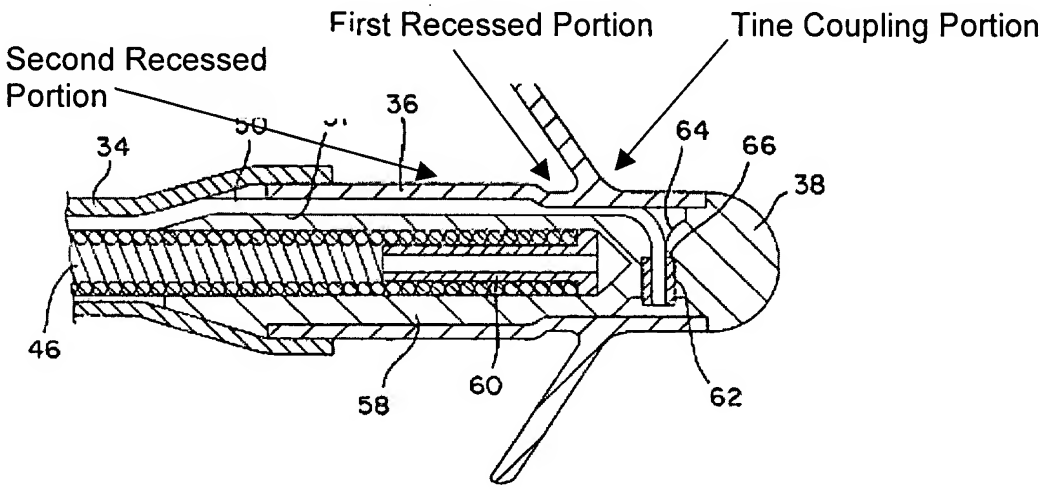
(8) Evidence Relied Upon

6,289,251	Huepenbecker et al.	09-2001
5,807,399	Laske et al.	09-1998
5,531,781	Alferness et al.	07-1996

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1, 3-4, 6-10, 12, 14-16, and 19-20 stand rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 6,289,251 ("Huepenbecker et al."). Huepenbecker et al. discloses a lead having at least one tine (40) coupled at the distal end thereof. The tines have a first position extended away from the lead body (as shown in Figure 4 reproduced below). In addition, although not explicitly stated, the tines necessarily have a second collapsed position because the tines of formed of a flexible material such that the tines folds/collapse against the lead body during insertion into the patient. The lead includes two recessed portions, as indicated on Fig. 4 reproduced below. The first recessed portion is longitudinally disposed between the tine-coupling portion and the second recessed portion, as shown below. In addition, when the tines collapse during implantation, the first recessed portion would necessarily be recessed away from the bottom surface of the tine.



With respect to claims 3, 9, and 19-20, the cross-sectional area of the first recessed portion is smaller than the cross-sectional area of the second recessed portion.

With respect to claim 4, it appears from Figure 4 that the cross-sectional area at the lead distal end (between electrode 38 and the tine- coupling portion) is approximately the same as the cross-sectional area of the tine-coupling portion. Accordingly, the cross-sectional area of the tine coupling area is necessarily "less than 10% smaller" than the cross-sectional area of the lead distal end.

With respect to claim 6, the length of the first recessed portion is less than the tine length.

With respect to claim 7, Examiner considers spacer 34 shown on Figure 4 to be an "intermediate portion of the lead body." As shown in Fig. 4, the diameters of the spacer 34, the first recessed portion, and the second recessed portion are each different from one another.

With respect to claim 8, the cross-sectional area of the first recessed portion is smaller than the cross-sectional area of the second recessed portion. As such, Examiner considers the first cross-sectional shape to be different from the second cross-sectional shape. In the alternative, Examiner notes that the 103 rejections below for claims 17-18 relate to modifying the first and/or second recessed areas to be non-circular (thus resulting in the first cross-sectional shape being different from the second cross-sectional shape).

With respect to claim 15, the lead disclosed in Huepenbecker et al. is necessarily formed by the method of claim 15.

Claims 1, 3-4, 6-10, 12, 14-16, and 19-20 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,807,399 ("Laske et al."). Laske et al. discloses a lead having at least one tine (124) coupled at the distal end thereof. The tines have a first position extended away from the lead body (as shown in Figure 5 reproduced below). In addition, although not explicitly stated, the tines necessarily have a second collapsed position because the tines of formed of a soft, pliant material such that the tines folds/collapse against the lead body during insertion into the patient (see col. 5, lines 23-37). The lead includes two recessed portions, as indicated on Fig. 5 reproduced below. The first recessed portion is longitudinally disposed between the tine-coupling portion and the second recessed portion, as shown below. In addition, when the tines collapse during implantation, the first recessed portion would necessarily be recessed away from the bottom surface of the tine.

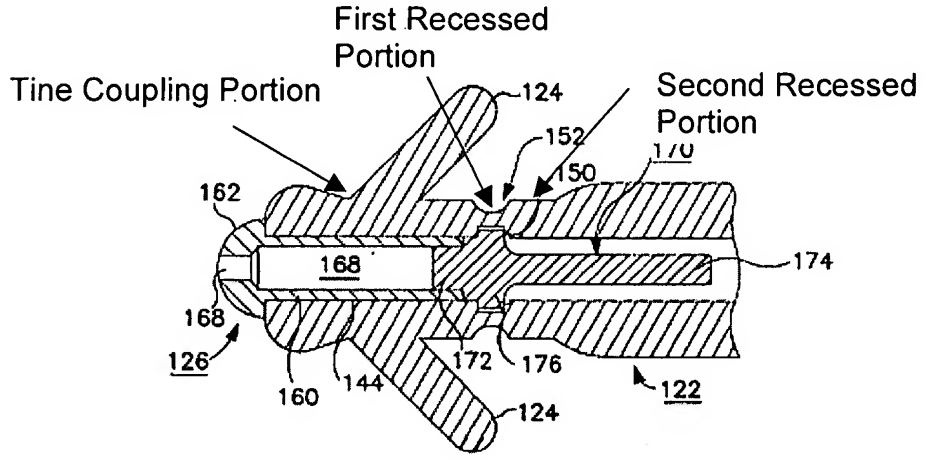


FIG. 5

With respect to claims 3, 9, and 19-20, the cross-sectional area of the first recessed portion is smaller than the cross-sectional area of the second recessed portion.

With respect to claim 4, it appears from Figure 5 that the cross-sectional area at the lead distal end is slightly larger than the cross-sectional area of the tine-coupling portion. Examiner considers the cross-sectional area of the tine coupling area to be approximately "less than 10% smaller" than the cross-sectional area of the lead distal end.

With respect to claim 6, the length of the first recessed portion is less than the tine length.

With respect to claim 7, Examiner considers tubular sheath 122 shown on Figure 5 to be an "intermediate portion of the lead body." As shown in Fig. 5, the diameters of the sheath 122, the first recessed portion, and the second recessed portion are each different from one another.

With respect to claim 8, the cross-sectional area of the first recessed portion is smaller than the cross-sectional area of the second recessed portion. As such, Examiner considers the first cross-sectional shape to be different from the second cross-sectional shape. In the alternative, Examiner notes that the 103 rejections below for claims 17-18 relate to modifying the first and/or second recessed areas to be non-circular (thus resulting in the first cross-sectional shape being different from the second cross-sectional shape).

With respect to claim 15, the lead disclosed in Laske et al. is necessarily formed by the method of claim 15.

Claims 2, 5, 11, 13, and 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,289,251 ("Huepenbecker et al.") in view of U.S. Patent No. 5,531,781 ("Alferness et al."). As discussed above, Huepenbecker et al. discloses a lead having two recessed portions at the tine interface section of the lead body. Huepenbecker et al. fails to disclose that the recessed portions extend only a portion around the perimeter of the lead body. Although not explicitly stated, it is well known in the art to utilize a space such as the recessed portions for receiving flexible tines during implantation, thereby minimizing the cross-section of the lead at the tine interface area during implantation. For example, Alferness et al. teaches a variety of embodiments in which a plurality of tines are received in a space or spaces formed within the lead body (see Figs. 6, 8, and 10 and corresponding text at col. 6, line 8 - col. 7, line 20). Such recesses are only required at the area in which the tines contact the lead body (see Figs. 8 and 10 and associated text). It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to modify the first and/or second recessed portions of Huepenbecker et al. such that recesses are created only at the area in which the tines contact the lead body as taught by Alferness et al. in order to ensure that lead body is sufficiently strong during implantation.

With respect to claim 5, Huepenbecker et al. fails to disclose that the lead body has a first transverse dimension and a second transverse dimension each at a longitudinal location along the first recessed portion, and the first transverse dimension

is greater than the second transverse dimension. Modifying the first recessed portion of Huepenbecker et al. such that recesses are created only at the area in which the tines contact the lead body as taught by Alferness et al., as described above, necessarily results in a lead body having a first transverse dimension which is greater than a second transverse dimension (see Figs. 8 and 10 of Alferness et al.).

With respect to claims 17-18, Huepenbecker et al. fails to disclose that forming the recessed portions includes forming non-circular cross-sections at the tine interface portion. Modifying the first and/or second recessed portions of Huepenbecker et al. such that recesses are created only at the area in which the tines contact the lead body as taught by Alferness et al., as described above, necessarily results in creating non-circular cross-sections.

Claims 2, 5, 11, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,807,399 ("Laske et al."). As discussed above, Laske et al. discloses a lead having two recessed portions at the tine interface section of the lead body. Laske et al. fails to disclose that the first recessed portion extends only a portion around the perimeter of the lead body. The first recessed portion (external groove 152) defines a zone in which the sheath 122 may be readily separated (see col. 7, lines 15-50). Laske et al. utilizes the first recessed portion to create a weakened area in the sheath 122. It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to modify the external groove 152 of Laske et al. such that it only extends around a portion of the perimeter of the lead body

(so long as the sheath 122 may be readily separated when force is applied thereto) in order to ensure that sheath 122 is sufficiently strong during implantation.

With respect to claim 5, Laske et al. fails to disclose that the lead body has a first transverse dimension and a second transverse dimension each at a longitudinal location along the first recessed portion, and the first transverse dimension is greater than the second transverse dimension. Modifying the external groove 152 of Laske et al. such that it only extends around a portion of the perimeter of the lead body, as described above, necessarily results in a lead body having a first transverse dimension that is greater than a second transverse dimension.

With respect to claim 17, Laske et al. fails to disclose that forming the first recessed portion includes forming a non-circular cross-section at the tine interface portion. Modifying the external groove 152 of Laske et al. such that it only extends around a portion of the perimeter of the lead body, as described above, necessarily results in creating a non-circular cross section.

Claims 13 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,807,399 ("Laske et al.") in view of U.S. Patent No. 5,531,781 ("Alferness et al."). As discussed above, Laske et al. discloses a lead having two recessed portions at the tine interface section of the lead body. Laske et al. fails to disclose that the second recessed portion extends only a portion around the perimeter of the lead body. Although not explicitly stated, it is well known in the art to utilize a space such as the second recessed portion for receiving flexible tines during implantation, thereby minimizing the cross-section of the lead at the tine interface area

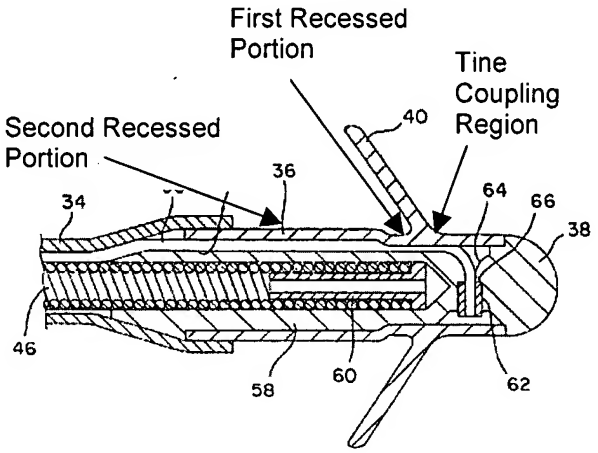
during implantation. For example, Alferness et al. teaches a variety of embodiments in which a plurality of tines are received in a space or spaces formed within the lead body (see Figs. 6, 8, and 10 and associated text). Such recesses are only required at the area in which the tines contact the lead body (see Figs. 8 and 10 and associated text). It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to modify the second recessed portion of Laske et al. such that the recess is created only at the area in which the tines contact the lead body as taught by Alferness et al. in order to ensure that sheath 122 is sufficiently strong during implantation.

With respect to claim 18, Laske et al. fails to disclose that forming the second recessed portion includes forming a non-circular cross-section at the tine interface portion. Modifying the second recessed portion of Laske et al. such that the recess is created only at the area in which the tines contact the lead body as taught by Alferness et al., as described above, necessarily results in creating a non-circular cross-section.

(10) Response to Argument

As an initial matter, Examiner would like to provide the following claim map in tabular form for independent claim 1 as to U.S. Patent No. 6,289,251 ("Huepenbecker et al."):

A lead assembly comprising:	
a lead body extending from a lead proximal end to a lead distal end and having an intermediate portion therebetween, the lead body including a tine interface section;	Huepenbecker et al. discloses a lead having a lead body 10, which includes a tine interface section in that at least one tine (40) is coupled at the distal end of the lead body to assist in fixation of the lead (see col. 2, lines 35-62).
at least one tine coupled with the lead body at a tine coupling portion, each at least one tine having a top surface and a bottom surface, the at least one tine having a first position extended away from the lead body, the at least one tine having a second collapsed position;	Huepenbecker et al. discloses at least one tine (40) coupled at the distal end of the lead. The tines have a first position extended away from the lead body (as shown in Figure 4). In addition, although not explicitly stated, the tines necessarily have a second collapsed position because the tines are formed of a flexible material such that the tines folds/collapse against the lead body during insertion into the patient.
at least one first recessed portion	The lead disclosed in Huepenbecker et al.

formed on the lead body at a first longitudinal location along the tine interface section of the lead body;	contains two recessed portions. Examiner has labeled which recess is considered to be the claimed "first recessed portion" as indicated on Fig. 4 reproduced below.
at least one second recessed portion formed on the lead body at a second longitudinal location along the section of the lead body;	The lead disclosed in Huepenbecker et al. contains two recessed portions. Examiner has labeled which recess is considered to be the claimed "second recessed portion" as indicated on Fig. 4 reproduced below.
the at least one first recessed portion longitudinally disposed between the tine coupling portion and the at least one second recessed portion; and	The first recessed portion is longitudinally disposed between the tine coupling portion and the second recessed portion, as indicated on Fig. 4 reproduced below: 
wherein the at least one first recessed portion is recessed away from the	When the tines collapse during implantation, the first recessed portion would necessarily

bottom surface of the at least one tine when the at least one tine is disposed in the second collapsed position.	be recessed away from the bottom surface of the tine because the bottom surface of tines would contact the outer surface of sleeve 36 (which forms the second recessed portion), thus leaving the first portion (which is illustrated as smaller in cross-section than the second recessed portion) recessed away from the bottom surface of the tine.

Applicant argues that Huenpenbecker does not teach a recessed portion recessed away from the bottom of the tine when the tine is disposed in a second collapsed position. In support of such an argument, Applicant notes that Huenpenbecker does not include any figures illustrating tines in a collapsed position and that there is no disclosure of the tines being recessed away from a first recessed portion. Examiner respectfully disagrees. Although not explicitly stated in Huenpenbecker, passive tines such as the ones illustrated in Huenpenbecker are necessarily are formed of a flexible material such that the tines fold/collapse against the lead body during insertion into the patient. In the Final Rejection, Examiner cited numerous patents to support this assertion (see, for example, U.S. Patent No. 5,531,781 to Alferness which teaches that tines are formed as flexible and pliant such that they collapse and do not interfere with or impede steering during implantation of the lead; see col. 6, lines 35-40. See also U.S. Patent No. 5,571,157 which describes that

tines flatten against the lead body thus reducing its diameters such that the tined lead is suitable for introduction through small blood veins; see col. 1, lines 45-55. In addition, see U.S. Patent No. 4,409,994 which teaches foldable tines which collapse against the lead body recessed portion during implantation of the lead). In order to implant the lead distal end at the heart such that it can provide the desired pacing or defibrillation therapy, the tines necessarily must fold down/collapse against the lead body such that the lead can be tracked through a patient's vasculature system to the implantation site of the right ventricular apex (see col. 2, line 59). When the tines collapse during implantation, the first recessed portion would necessarily be recessed away from the bottom surface of the tine because the bottom surface of tines would contact the outer surface of sleeve 36 (which forms the second recessed portion), thus leaving the first portion (which is illustrated as smaller in cross-section than the second recessed portion) recessed away from the bottom surface of the tine.

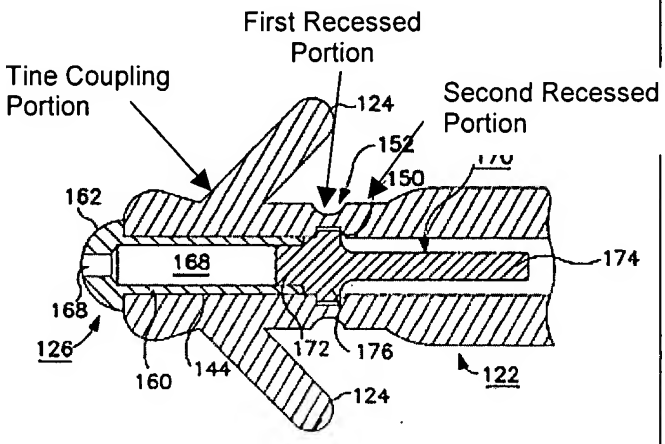
In addition, Applicant argues the statement made in the Final Office Action that Figure 4 of Huenpenbecker illustrates that the cross-sectional area of the first recessed portion is smaller than the cross-sectional area of the second recessed portion because Figure 4 illustrates the cross-section of the lead taken only along a single axial plane. Examiner respectfully disagrees. The axial view of Figure 4 shows the diameter of the first recessed portion to be smaller than the diameter of the second recessed portion. Since cross-sectional area is a direct function of diameter size, Examiner maintains that the cross-sectional area of the first recessed portion must necessarily be smaller than the cross-sectional area of the second recessed portion.

With respect to claim 4, Applicant's argues that since Huenpenbecker does not state that the drawings are to scale, the Figure 4 of Huenpenbecker cannot anticipate the claim 4 of the present invention. Examiner respectfully disagrees. Claim 4 requires that the first cross-section area be less than 10% smaller than the second cross-sectional area. "Less than 10% smaller" includes areas that are between 1-9% smaller, as well as equal areas or areas that larger than the second area. Examiner maintains that Figure 4 illustrates that the cross-sectional area at the lead distal end (between electrode 38 and the tine- coupling portion) is approximately the same as the cross-sectional area of the tine-coupling portion. As such, the cross-sectional area of the tine coupling area is approximately equal to the cross-sectional area of the lead distal end, and thus necessarily "less than 10% smaller" than the cross-sectional area of the lead distal end.

With respect to claims 7 and 8, Applicant argues that Huenpenbecker et al. does not disclose the cross-sectional areas of the first and second recessed portions. Examiner respectfully disagrees. Since the axial view of Figure 4 shows the diameter of the first recessed portion to be smaller than the diameter of the second recessed portion, Examiner considers the cross-sectional area of the first recessed portion to be different from the second cross-sectional shape. In essence, Examiner considers the broadest reasonable interpretation of the "different shape" to encompass identical figures of different sizes.

Moving to arguments pertaining to the Laske et al. reference, as an initial matter, Examiner would like to provide the following claim map in tabular form for independent claim 1 as to U.S. Patent No. 5,807,399 ("Laske et al."):

A lead assembly comprising:	
a lead body extending from a lead proximal end to a lead distal end and having an intermediate portion therebetween, the lead body including a tine interface section;	Laske et al. discloses a lead having a lead body 10, which includes a tine interface section in that at least one tine (40) is coupled at the distal end of the lead body to assist in fixation of the lead (see col. 5, lines 9-37).
at least one tine coupled with the lead body at a tine coupling portion, each at least one tine having a top surface and a bottom surface, the at least one tine having a first position extended away from the lead body, the at least one tine having a second collapsed position;	Laske et al. discloses at least one tine (40) coupled at the distal end of the lead. The tines have a first position extended away from the lead body (as shown in Figure 5). In addition, although not explicitly stated, the tines necessarily have a second collapsed position because the tines of formed of a soft, pliant material such that the tines folds/collapse against the lead body during insertion into the patient (see col. 5, lines 23-37).

at least one first recessed portion formed on the lead body at a first longitudinal location along the tine interface section of the lead body;	The lead disclosed in Laske et al. contains two recessed portions. Examiner has labeled which recess is considered to be the claimed "first recessed portion" as indicated on Fig. 5 reproduced below.
at least one second recessed portion formed on the lead body at a second longitudinal location along the section of the lead body;	The lead disclosed in Laske et al. contains two recessed portions. Examiner has labeled which recess is considered to be the claimed "second recessed portion" as indicated on Fig. 5 reproduced below.
the at least one first recessed portion longitudinally disposed between the tine coupling portion and the at least one second recessed portion; and	The first recessed portion is longitudinally disposed between the tine coupling portion and the second recessed portion, as indicated on Fig. 5 reproduced below:  FIG. 5

wherein the at least one first recessed portion is recessed away from the bottom surface of the at least one tine when the at least one tine is disposed in the second collapsed position.	When the tines collapse during implantation, the first recessed portion would necessarily be recessed away from the bottom surface of the tine because the bottom surface of tines would contact the outer surface lead body (which forms the second recessed portion), thus leaving the first portion or groove 152 (which is illustrated as smaller in cross-section than the second recessed portion) recessed away from the bottom surface of the tine.

Applicant argues that Laske does not teach a recessed portion recessed away from the bottom of the tine when the tine is disposed in a second collapsed position. In support of such an argument, Applicant notes that Laske does not include any figures illustrating tines in a collapsed position and that there is no disclosure of the tines being recessed away from a first recessed portion. Examiner respectfully disagrees. Although not explicitly stated in Laske, tines such as the ones illustrated in Laske are necessarily are formed of a flexible material such that the tines fold/collapse against the lead body during insertion into the patient. In the Final Rejection, Examiner cited numerous patents to support this assertion (see, for example, U.S. Patent No. 5,531,781 to Alferness which teaches that tines are formed as flexible and pliant such

that they collapse and do not interfere with or impede steering during implantation of the lead; see col. 6, lines 35-40. See also U.S. Patent No. 5,571,157 which describes that tines flatten against the lead body thus reducing its diameters such that the tined lead is suitable for introduction through small blood veins; see col. 1, lines 45-55. In addition, see U.S. Patent No. 4,409,994 which teaches foldable tines which collapse against the lead body recessed portion during implantation of the lead). More specifically, Laske incorporates by reference U.S. Patent No. 3,902,501 to Citron et al., which teaches that the tines fold/collapse against the lead body during insertion into the patient (see Figures 6 and 11 of Citron et al. and associated text). In order to implant the lead distal end at the heart such that it can provide the desired pacing therapy, the tines necessarily must fold down/collapse against the lead body such that the lead can be tracked through a patient's vasculature system to the implantation site of the endocardium. When the tines collapse during implantation, the first recessed portion would necessarily be recessed away from the bottom surface of the tine because the bottom surface of tines would contact the outer surface lead body (which forms the second recessed portion), thus leaving the first portion or groove 152 (which is illustrated as smaller in cross-section than the second recessed portion) recessed away from the bottom surface of the tine.

In addition, Applicant argues the statement made in the Final Office Action that Figure 5 of Laske illustrates that the cross-sectional area of the first recessed portion is smaller than the cross-sectional area of the second recessed portion because Figure 4 illustrates the cross-section of the lead taken only along a single axial plane. Examiner

respectfully disagrees. The axial view of Figure 5 shows the diameter of the first recessed portion to be smaller than the diameter of the second recessed portion. Since cross-sectional area is a direct function of diameter size, Examiner maintains that the cross-sectional area of the first recessed portion must necessarily be smaller than the cross-sectional area of the second recessed portion.

With respect to claim 4, Applicant's argues that since Laske does not state that the drawings are to scale, the Figure 5 of Laske cannot anticipate the claim 4 of the present invention. Examiner respectfully disagrees. Claim 4 requires that the first cross-section area be less than 10% smaller than the second cross-sectional area. "Less than 10% smaller" includes areas that are between 1-9% smaller, as well as equal areas or areas that larger than the second area. Examiner maintains that Figure 5 illustrates that the cross-sectional area at the lead distal end (between electrode 126 and the tine- coupling portion) is approximately the same as the cross-sectional area of the tine-coupling portion. As such, the cross-sectional area of the tine coupling area is approximately equal to the cross-sectional area of the lead distal end, and thus necessarily "less than 10% smaller" than the cross-sectional area of the lead distal end.

With respect to claims 7 and 8, Applicant argues that Laske et al. does not disclose the cross-sectional areas of the first and second recessed portions. Examiner respectfully disagrees. Since the axial view of Figure 5 shows the diameter of the first recessed portion to be smaller than the diameter of the second recessed portion, Examiner considers the cross-sectional area of the first recessed portion to be different from the second cross-sectional shape. In essence, Examiner considers the broadest

reasonable interpretation of the "different shape" to encompass identical figures of different sizes.

With respect to claims 2, 5, 11, 13, and 17-18, Applicant next argues that the motivation statement to combine Huenpenbecker (or Laske) and Alferness et al. is unsupported by the references. The motivation to combine the references (to ensure that the lead body is sufficiently strong during implantation) is based on common sense and in the knowledge generally available to one of ordinary skill in the art. Alferness is directed to an implantable lead having a steerable tip at the distal end of the lead such that the lead can be steered along a desired path as the lead is implanted (see, for example, Alferness at col. 1, lines 8-15). The lead must be sufficiently strong to be tracked/maneuvered around corners, past branches, and across constrictions (see Alferness at col. 1, lines 56-67). Thus, Alferness teaches the necessity and desirability of ensuring that the lead body is sufficiently strong during implantation. Further, Examiner maintains that added material in the area of the recesses 167, as shown in Figure 10 of Alferness et al., would necessarily strengthen the lead body at the distal end thereof such that it is sufficiently strong to be tracked through a patient's vasculature system to the implantation site of the endocardium.

Lastly, with respect to claims 2, 5, 11, 13, and 17-18, Applicant argues that Laske et al. teaches away from making the selective modifications to make a lead stronger because the purpose of element 152 is to create a weakened portion. However, it is Examiner's position that to modifying the external groove 152 of Laske et al. such that it only extends around a portion of the perimeter of the lead body in order to ensure that

sheath 122 is sufficiently strong during implantation is consistent with the teachings of Laske. So long as the sheath 122 may be readily separated when force is applied thereto, it would be desirable to modify the distal end of the lead as described in the rejection above to ensure that sheath 122 is sufficiently strong to be tracked to the implantation site without breaking.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Nicole R. Kramer

Conferees:

Angela Sykes

Scott Getzow

ANGELA D. SYKES
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700